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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,625

10/23/2003

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

MAIL DATE

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11/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,625	Applicant(s) THERIN ET AL.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-11 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-11, and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This action is in response to the applicant's amendment received 30 June 2009. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 2, 7, 12, and 13 remain cancelled. Claims 19-23 remain withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6, 8-10, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt (U.S. Patent No. 6,042,592) in view of Scetbon (U.S. Patent No. 6,406,423 B1). Schmitt discloses a composite prosthesis for reinforcement of a tissue structure (see entire document) comprising a porous textile support that includes an arrangement of threads each composed of filaments of non-absorbable

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polymer material (polyester) forming a two-dimensional knitted structure, and a non-continuous film enveloping and penetrating into the arrangement of threads, occluding the microporous structure (for example, see column 5, lines 55-65), but not the macroporous texture (52; for example, see column 6, lines 57-63). Schmitt fails to disclose a portion of the macroporous texture is occluded. Also, Schmitt discloses the film may be a polymeric material, but fails to disclose specifically that the film is hydrophilic absorbable material.

Schmitt discloses the size of the macropores may be modified. The applicant has failed to disclose occluding portions of the macroporous texture provides an advantage, is used for a particular purpose, or solves a stated problem, and it appears a prosthesis having a macroporous structure that is not occluded over the entire protected zone would perform equally well especially since the applicant indicates as such in the specification. Since one having ordinary skill in the art could have occluded portions of the macroporous structure and the applicant has not disclosed any benefit of doing so, such a modification would have been an obvious matter of design choice at the time of the invention.

Scetbon discloses a prosthesis for reinforcement of a tissue structure comprising a film (see entire document). Scetbon teaches the film is hydrophilic and absorbable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Schmitt's film of a hydrophilic absorbable material as taught by Scetbon. Doing so would reduce erosion and sclerosis of supported tissue to a minimum (for example, see column 4, lines 3-5).

With further respect to claims 4 and 5, Schmitt's film encapsulates the prosthesis which is disclosed as being 0.05 mm - 0.5 mm, thus the film has a thickness of about 0.05mm - 0.5mm. To modify the thickness of the prosthesis such that the film has a thickness of less than or equal to 500 microns, or from 10-100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

With further respect to claims 8-10, Schmitt in view of Scetbon discloses the textile support is rectangular with parallel edges (for example, see Figure 7), but fails to disclose the shape recited in claim 10. The applicant has not disclosed that a strip with curved edges provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with straight edges because the function of the prosthesis is to act as a reinforcement for tissue structures and this function is not affected by its shape. Therefore, it would have been obvious to modify Schmitt's in view of Scetbon prosthesis to obtain the invention recited in claim 10.

With further respect to claim 14, it would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the absorbable material from the group formed by collagens, polysaccharides, and their mixtures, since it has been held to be within the general skill of a worker to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt and Scetbon as applied to claim 1 above, and further in view of Landgrebe et al. (EP 0774240 A1).

Schmitt in view of Scetbon discloses the claimed invention except for a prosthesis having nonparallel edges and a bulged central region. Landgrebe et al. disclose a strip (Figure 1, not labeled) having nonparallel edges (top edge 2 and bottom edge not labeled). Figure 1 shows the device is bulged in the central region (1) and narrower at the ends (5, 6, 7, and 8). This configuration allows the device to support a wide surface area of an organ (bladder; column 1, lines 45-47), thus contributing to a reliable treatment of incontinence in cases of extreme weakness of the pelvic floor with prolapsing anatomical displacement of the organs of the lesser pelvis (column 1, lines 33-39). Therefore, to construct Schmitt's in view of Scetbon having nonparallel edges and a bulge as taught by Landgrebe et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to support prolapsed structures on a large surface area.

Response to Arguments

Applicant's arguments filed 30 June 2009 have been fully considered but they are not persuasive. The applicant argues that Schmitt fails to disclose the macroporous texture of the textile support in a second portion of the protected zone is occluded by the film and Scetbon and Landgrebe fail to remedy this deficiency. However, the applicant discloses in the specification that the claimed invention contemplates occluding the macroporous texture over the whole protected zone, over a portion of the

zone, or over no part of the zone (i.e., only coating the individual threads to occlude the microporous texture) thus indicating the embodiments are all obvious variations. It is the examiner's position that to modify Schmitt's textile support as recited in the amended claims would have been an obvious matter of design choice at the time of the invention (see new rejection above for details).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE TYSON** whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
October 27, 2009

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773